

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

MISSION PHARMACAL COMPANY, §

Plaintiff, §

v. §

VIRTUS PHARMACEUTICALS, LLC, §

Defendant. §

**CIVIL ACTION NO.:
5:13-cv-00176-OLG**

JURY TRIAL DEMANDED

DEFENDANT'S REPLY IN SUPPORT OF MOTION TO AMEND SCHEDULING ORDER

Mission Pharmacal Company ("Mission")'s Opposition to the Motion to Amend the Scheduling Order ("Motion to Amend") filed by Virtus Pharmaceutical, LLC's ("Virtus") largely ignores all substantive points made by Virtus and fails to address the benefits of a patent scheduling order with specific deadlines for detailed invalidity contentions and responses.

1. Mission Misses the Point of a Markman Hearing and Invalidity Contention Dates.

Mission's brief makes it abundantly clear that Mission has not contemplated the possibility that Virtus' products do not infringe. However, contrary to Mission's assumption of liability here, Virtus has valid non-infringement and invalidity arguments that deserve a fair review. As fully set forth in Virtus's initial brief in support of the Motion to Amend, the '247 Patent has multiple terms that need to be construed. To that end, the parties need the Court's claim construction because *until then* the expert's opinions will be incomplete, fragmented, possibly contradictory, and reliant upon incorrect data. The products-in-suit will need to be tested in a laboratory.¹ The parties will need the help of the Court to determine the proper testing

¹ In order to determine whether an iron compound is selected to be "rapidly dissolving" or "slowly dissolving" the iron dissolution rate will need to be tested. (Col. 13, Ln. 22-42)

protocols as “described” under the ‘247 Patent because determining the correct testing protocols is very difficult, if not impossible.² If no claim construction occurs before the close of discovery or trial, the parties will need to engage in multiple costly laboratory tests for each of the various possible constructions.

Assuming the ‘247 Patent is not indefinite, and the Court is able to determine which testing protocol the ‘247 Patent teaches, then experts will need to evaluate the products-in-suit according to that protocol. Without a separate claim construction hearing, each expert will need to prepare multiple, different constructions depending on how the Court ends up construing the claims at trial. It would be inefficient and confusing to require the experts to come prepared to evaluate the products-in-suit with multiple, alternative claim constructions to support non-infringement, invalidity for indefiniteness, and invalidity.

Virtus explained in its initial brief that the ‘247 Patent is complicated and will require detailed claim construction. *See* Defendant’s Initial Brief at 9-11 [Dkt. 32]. Mission effectively concedes this point, yet essentially urges the court to ignore the complexity and rush the case regardless. Indeed, Mission never explains why it would be a good idea to handle this case under the current Scheduling Order other than it desires a quick trial (regardless of the consequences). Additionally, Mission neglects to discuss the financial cost of preparing for multiple, different claim constructions including investigations and experts to support each. Most importantly, Mission provides no advantages, no evidence, and no arguments; Mission only explains that amending the Scheduling Order will cause delay.

Moreover, to the extent Mission concedes to some sort of *Markman* hearing, it fails to

² *Id.* For example, compare testing with pH of gastrointestinal fluid with pH of saliva. The dissolution time in gastrointestinal fluid, with a highly acidic pH value, will be substantially different than the dissolution time in saliva, which has only a slightly acidic pH value. Thus, the pH value in the testing protocol—just one of many variables—can significantly alter the testing results and infringement analysis.

concede to the usual (or a realistic) timeframe that is necessary to handle the process. Indeed, it is unrealistic to agree to a *Markman* hearing, but only to the extent it has no effect on the current schedule. Incorporating a Markman hearing under the current schedule would inevitably require setting the hearing after expert disclosures (which begin in two weeks), thereby eliminating one of the primary benefits of a Markman hearing—controlling costs by narrowing and clarifying the issues for the experts. Mission also fails to address the benefits of separate invalidity contentions, as adopted by at least fifteen districts to put the parties on a clear schedule to propose and counter the question of validity. Indeed, as explained by one district court, early disclosure in patent cases is “designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *MEMC Electronic Materials v. Mitsubishi Materials Silicon Corp.*, 2004 WL 5363616, at *4 (N.D. Cal. 2004).

2. The *PureTek* Case Demonstrates the Need for an Amended Scheduling Order.

Mission’s praise for the scheduling order in the *PureTek*³ matter is undermined by the problems that already have occurred in that case. The *PureTek* case uses the same type of non-patent discovery schedule presently entered in this case. See *PureTek* Scheduling Order [Puretek Dkt. 16] (*PureTek* case documents collectively attached as Ex. A). No *Markman* hearing was scheduled. With less than a month remaining in discovery, PureTek moved to disqualify Mission’s expert, arguing that he did not actually provide arguments as to how the claims should be construed. See Ex. A [PureTek Dkt. 24]. Mission responded that its expert was never intended to serve that purpose, asserting that claim construction is the job of the Court, not the expert. See Ex. A [PureTek Dkt. 26]. If a *Markman* hearing had been scheduled in *PureTek*, it would have been clear that Mission’s expert was an infringement expert—used to apply the

³ *Mission Pharmacal Company v. PureTek Corporation*, Case No. 5:12-cv-00920-OLG

Court's claim construction to the facts of the case thereby eliminating the confusion and expansion of proceedings that has now occurred. Indeed, Mission's reliance on the *PureTek* scheduling order only shows why Virtus's proposed order is a better option.

3. Mission Fails to Address the Prejudice Caused to Virtus

Mission argues that the current Scheduling Order can handle all of the relevant patent-related issues through discovery, but so far Mission has not provided the information that that Virtus needs for its defense. For example, the Mission's claim charts provided to Virtus are at best, inadequate. It is apparent to Virtus that Mission did not test the iron dissolution rates of Virtus's products, but merely relied upon ingredient listings.⁴ As a result, Virtus believes that Mission (wrongly) assumed that Virtus's products were identical to those of other competitors and that no detailed claim construction is necessary and the charts do not construe any relevant terms. One of the referenced claim charts, without settlement related letter, is attached as Ex. B, and is not offered for any purpose prohibited under FRE 408(a), but rather in response to Mission's claims that providing those charts has somehow eliminated the need for a *Markman* hearing or patent specific procedures.

While the claim charts identify claimed elements and then suggest that Virtus's products comprise those elements, not one claim is construed and no terms are defined. Further, Mission's claim charts blindly assert, apparently without the benefit of testing, that the ferrous gluconate in the products-in-suit will dissolve in less than 3 hours following oral administration. Ex. B, p. 5, Claim 25. There is no evidence cited to support this proposition. In fact, the '247 Patent suggests circumstances where this might not be the case. *See* '247 Patent, Col. 13, Ln. 43-50. Moreover, since the claim charts are provided under FRE 408, Virtus is prohibited from

⁴ If Mission did test the dissolution rate of iron in Virtus's products, they did not produce the test results. Nor is any testing data identified or relied upon in the claim charts they provided.

using them for substantive purposes in the case). The amended scheduling order would require Mission to produce information that it should provide--and that Virtus has requested--but which Mission has so far not produced.

A *Markman* hearing before discovery concludes and separate from trial will be necessary to properly determine the meaning of the '247 Patent—if there is any at all. For example, if Mission had thoroughly investigated the products-in-suit, it would have discovered that the ferrous gluconate in the products-in-suit is in sustained released pellets that are pH independent and provide sustained delivery of iron for more than 3 hours, and therefore was selected to be a “slowly dissolving iron compound.” Any alternative construction of the '247 Patent that would define the products-in-suit's ferrous gluconate sustained release pellets to be “rapidly dissolving” would necessarily make the '247 Patent indefinite. On the other hand, Mission prefers to have the Court handle claim construction after discovery, which will inevitably create confusion by providing the opportunity for experts to come to trial with multiple, perhaps contradictory, constructions of non-infringement and invalidity. Of course, this gets at the ultimate purpose and efficiency of *Markman* hearings in patent cases – the parties, the Court, and the jury are left with a much clearer path to trial, with the added benefit that *Markman* hearings often give the parties the necessary information to settle the case during the discovery process.

4. Virtus Is More Than Willing to Work With Mission on Scheduling

Mission's briefing reflects a fundamental misunderstanding of Virtus's position on scheduling. Prior to filing its present Motion to Amend, on May 31, 2013, Virtus requested to Mission (through counsel) that the parties amend the Scheduling Order because several terms needed to be construed, and once construed, the case “will be much easier to resolve.” See Mission Opposition, Ex. 3 [Dkt. 37-3]. Virtus attempted to have an open dialogue prior to filing

its motion and provided specific dates. Virtus also noted that claim construction hearing should occur “early in the case before the parties expend large amounts of money on expert discovery...” *See id.* At no point did Virtus communicate that it was “unwilling to discuss a *Markman* procedure that does not involve a 1 ½ year delay” as Mission asserts in its Response. *See* Mission Opposition at 2 [Dkt. 37]. Rather, Counsel for Virtus stated, “We are amenable to discussing the movement of the dates...but we believe the dates are reasonable.” *See* Dkt. 37-3. Indeed, Virtus remains willing to discuss any scheduling order proposed by Mission that adequately provides for discovery and claim construction.

Conclusion

Mission is not entitled to steamroll non-infringing competitors under the guise of “avoiding delay.” If this case continues on a non-patent discovery schedule without a *Markman* hearing, Virtus is limited in its ability to defend the claims brought against it and to investigate Mission’s own product and patent marking. Virtus respectfully requests that the Court amend the Scheduling Order to allow for claim construction briefing and a *Markman* hearing.

Date July 25, 2013

Respectfully submitted,

/s/ W. Scott Creasman

William B. Nash

Texas Bar No. 14812200

bill.nash@haynesboone.com

Jason Whitney - TX Bar No. 24066288

jason.whitney@haynesboone.com

HAYNES AND BOONE, LLP

112 East Pecan Street, Suite 1200

San Antonio, Texas 78205

Telephone: (210) 978-7000

Facsimile: (210) 554-0484

W. Scott Creasman – GA Bar No. 194860

screasman@taylorenghish.com

Jeffrey R. Kuester – GA Bar No. 429960
jkuester@taylorenghish.com
Amanda G. Hyland – GA Bar No. 325115
ahyland@taylorenghish.com
Brett Bartel – GA Bar No. 508052
bbartel@taylorenghish.com
TAYLOR ENGLISH DUMA LLP
1600 Parkwood Circle, Suite 400
Atlanta, Georgia 30339
Telephone: (770) 434-6868
Facsimile: (770) 434-7376

Admitted *Pro Hac Vice*

ATTORNEYS FOR DEFENDANT
VIRTUS PHARMACEUTICALS, LLC

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 25, 2013, a copy of this instrument was electronically filed with the United States District Court for the Western District of Texas, San Antonio Division, with notice of case activity to be generated and sent electronically by the Clerk of the Court to all counsel of record and mailed by United States Postal Service to all non-CM/ECF participants.

s/ W. Scott Creasman
W. Scott Creasman
ATTORNEY FOR DEFENDANT
VIRTUS PHARMACEUTICALS, LLC